



AUG - 4 1995

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Madison, NJ 07940-0874

Re: Patent Term Extension
Application for
U.S. Patent No. 4,535,186

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,535,186 issued August 13, 1985, which claims the human drug product EFFEXOR® (venlafaxine hydrochloride), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be five years.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of August 30, 1994. Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= 1/2 \text{ (Testing Phase) + Approval Phase} \\ &= 1/2 (1981) + 978 \\ &= 1,969 \text{ days}\end{aligned}$$

Since the regulatory review period began November 23, 1985, after the patent issue date, the entire period has been considered in the above determination. No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

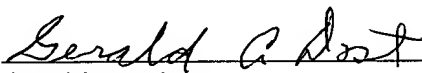
The five year limitation of 35 U.S.C. § 156(g)(6)(A) applies in the present situation because the patent was issued after the date of enactment (September 24, 1984) of 35 U.S.C. § 156. Since the period of extension calculated under 35 U.S.C. § 156(c) for the patent cannot exceed five years under 35 U.S.C. § 156(g)(6)(A), the period of extension will be for five years.

The 14 year exception of 35 U.S.C. § 156(c)(3) does not operate to further reduce the period of extension determined above.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Commissioner will issue a certificate of extension, under seal, for a period of five years.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	4,535,186
Granted:	August 13, 1985
Applicant:	G. E. Morris Husbands et al.
Owner of Record:	American Home Products Corporation
Title:	2-PHENYL-2-(1-HYDROXYCYCLOALKYL OR 1- HYDROXYCYCLOALK-2- ENYL)ETHYLAMINE DERIVATIVES
Classification:	564/336
Product Trade Name:	EFFEXOR
Term Extended:	Five years


Gerald A. Dost
Senior Legal Advisor
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cc: Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fisher's Lane, Room 11-44
Rockville, MD 20857

RE: EFFEXOR
FDA Docket No.: 94E-0098